IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC., Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services; and MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration, Defendants.	)	10 Civ. 5690 (AKH) (AJP)

MEMORANDUM OF LAW IN SUPPORT OF
PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Triclosan and triclocarban are chemicals commonly found in "antibacterial" personal care products such as liquid and bar soaps. Exposure to these chemicals has been linked to serious health harm through disruption of hormones critical for normal development and function of the brain and the reproductive system. Triclosan use may also undermine the effectiveness of antibiotics by contributing to the development of drug-resistant bacteria. Antimicrobial products are widespread on the market, resulting in substantial human exposure to triclosan and triclocarban.

More than three decades have passed since the United States Food and Drug Administration ("FDA") proposed regulation of topical antimicrobial drug products, including those that contain triclosan and triclocarban, for over-the-counter human use. Under federal law, the agency must either establish the safety, effectiveness, and labeling accuracy of products containing these chemicals, or prohibit the marketing of the products. The FDA has done neither, despite its recognition of mounting evidence that triclosan and triclocarban pose significant health risks and are not more effective than washing with regular soap and water. This decades-long delay prolongs avoidable exposure to triclosan and triclocarban and threatens the health of consumers.

The FDA's failure to act defies reason and violates the Administrative Procedure Act ("APA"), 5 U.S.C. § 555(b), and the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355. The effect of the agency's delay is to permit the proliferation of triclosan and triclocarban products. But without a final agency determination, interested parties are prevented from challenging the merits of the FDA's de facto finding that the drugs are safe and effective. Prompt resolution of this case is appropriate and necessary to effectuate congressional will and

protect public health. Pursuant to the APA, 5 U.S.C. § 706(1), the Court should declare unreasonable the FDA's delay and order the agency to finalize its regulation of antimicrobial products within ninety days.

STATUTORY FRAMEWORK

The FFDCA charges the FDA with "protect[ing] the public health by ensuring that . . . drugs are safe and effective." 21 U.S.C. § 393(2)(B).[1] The statute prohibits the introduction of any new drug into interstate commerce unless the FDA has approved an application for the drug and the approval remains effective. 21 U.S.C. § 355(a). The FFDCA defines "drugs" as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." *Id.* § 321(g)(1). A "new drug" is "[a]ny drug" that "is not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." *Id.* § 321(p).

Congress amended the FFDCA in 1962 "[t]o protect the public health" and "assure the safety, effectiveness, and reliability of drugs." Pub. L. No. 87-781, 76 Stat. 780, 780 (1962); *see also United States v. Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 798 (1969) ("[T]he Act's overriding purpose [is] to protect the public health . . . ."). As amended, the FFDCA prohibits the FDA from approving a new drug if, under the conditions of use recommended by the proposed labeling, (1) the drug is unsafe or (2) there is insufficient information that the drug is safe, or (3) there is inadequate evidence that the drug will have the effects purported by its labeling. 21 U.S.C. § 355(d).

To accomplish its statutory duty under the 1962 amendment, the FDA adopted procedures to evaluate all marketed drugs for efficacy. *See Weinberger v. Bentex Pharm., Inc.*,

[1] Defendants FDA, Kathleen Sebelius, and Margaret Hamburg are individually and collectively referred to as "the FDA."

412 U.S. 645, 650 (1973). The regulations contain criteria for determining whether a drug must be restricted to use by prescription of a physician or may be marketed over-the-counter. The agency regulates the safety and effectiveness, as well as labeling accuracy (referred to as "misbranding"), of over-the-counter drugs through a monograph procedure.[2] 21 C.F.R. § 330.10. Pursuant to this procedure, the FDA appoints an Advisory Review Panel ("Panel") of qualified experts for each designated category of over-the-counter drugs (e.g. cough and cold, antacid). *See id*. § 330.10(a)(1). A Panel reviews data submitted by interested parties and recommends a proposed monograph that states the conditions under which the drugs would be generally recognized as safe, effective, and not misbranded. *See id.* § 330.10(a)(2)-(5).

After reviewing the recommendations of a Panel, the FDA publishes a proposed order in the Federal Register that allows for public comment. The proposed order contains: (1) a monograph establishing conditions under which the drugs, either individually or as a category, are generally considered safe, effective, and not misbranded ("Category I"); (2) a statement of conditions excluded from the monograph because they would result in a drug's not being generally recognized as safe and effective or would result in misbranding ("Category II"); and (3) a statement of conditions excluded from the monograph because there are insufficient data to classify their safety, effectiveness, or accuracy of branding ("Category III"). *Id.* § 330.10(a)(6)(i)-(iii). The proposed order must also specify a reasonable time period within

[2] A drug is "safe" if it has "low incidence of adverse reactions or significant side effects under adequate directions for use and warnings against unsafe use as well as low potential for harm which may result from abuse under conditions of widespread availability." 21 C.F.R. § 330.10(a)(4)(i). A drug is "effective" if there is "a reasonable expectation that, in a significant proportion of the target population, the pharmacological effect of the drug, when used under adequate directions for use and warnings against unsafe use, will provide clinically significant relief of the type claimed." *Id.* § 330.10(a)(4)(ii). A drug is "misbranded" if it is "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j).

which Category III conditions are permitted to remain in marketed products while the FDA obtains data necessary for their evaluation. *Id.* § 330.10(a)(6)(iv).

After considering comments and any new information, the FDA publishes a tentative order establishing conditions under which a category of over-the-counter drugs is generally recognized as safe and effective and not misbranded. *Id.* § 330.10(a)(7)(i). After reviewing further comments and objections, the FDA publishes a final monograph. *Id.* § 330.10(a)(9). Following publication of a final monograph, the agency prohibits over-the-counter drug products containing non-monograph conditions – that is, Category II and III drugs that are not safe and effective, or for which there are insufficient data establishing safety and efficacy – from being introduced into interstate commerce after a specified date. *See Cutler v. Kennedy*, 475 F. Supp. 838, 855 (D.D.C. 1979); FDA, Tentative Final Monograph for Health-Care Antiseptic Drug Products, 59 Fed. Reg. 31402, 31403 (June 17, 1994) [hereinafter 1994 Tentative Monograph], Ex. 5 to Declaration of Vivian H.W. Wang ("Wang Decl.").

FACTUAL BACKGROUND

Triclosan and triclocarban are common ingredients in "antibacterial" products for both consumers and healthcare professionals. Declaration of Dr. Sarah Janssen ¶ 10 ("Janssen Decl."). Adults and children are exposed to the chemicals when they wash their hands or bathe with products containing triclosan or triclocarban, because the chemicals are rapidly absorbed through the skin and enter the bloodstream. *Id.* ¶¶ 13-14. A study by the U.S. Centers for Disease Control and Prevention found triclosan residues in the urine of seventy-five percent of Americans over the age of six. *Id.* ¶ 13. Triclosan has also been detected in human breast milk, suggesting that exposure occurs in infants who are undergoing vulnerable periods of development. *Id.*

Harms Posed by Triclosan and Triclocarban

Exposure to triclosan and triclocarban poses significant health risks. Janssen Decl. ¶¶ 16-25. Triclosan has been linked to decreased thyroid hormone levels, which are essential to normal development of the brain and nervous system. *Id.* ¶ 17. Interference with thyroid hormones may also cause reproductive problems, including infertility, in both men and women. *Id.* ¶¶ 17-18. Recent studies have shown that triclosan and triclocarban may amplify the effect of sex hormones, interfering with reproductive development and stimulating growth of hormone-dependent cancers. *Id.* ¶ 19.

In addition, studies have shown that triclosan may promote antibiotic resistance in bacteria. Janssen Decl. ¶ 25. Because bacteria that become resistant to triclosan and triclocarban may also develop "cross-resistance" to other antibiotics, widespread use of these chemicals may undermine the effectiveness of antibiotics needed to treat infections. *See id.*

Although manufacturers market products containing triclosan and triclocarban as having "antibacterial" properties, studies have shown that consumer soaps containing these chemicals offer no additional health benefit compared to regular soaps. *Id.* ¶ 26. The FDA has acknowledged the inadequacy of data supporting the effectiveness of triclosan and triclocarban. *See* FDA, Triclosan: What Consumers Should Know (Apr. 8, 2010), http://www.fda.gov/forconsumers/consumerupdates/ucm205999.htm [hereinafter FDA Website], Ex. 7 to Wang Decl. ("At this time, FDA does not have evidence that triclosan added to antibacterial soaps and body washes provides extra health benefits over soap and water.").

Furthermore, the agency has long been aware of the lack of data supporting the safety of these chemicals. In 1974, the FDA-appointed Panel on over-the-counter antimicrobial products identified studies that linked triclosan and triclocarban to brain, spleen, and liver damage. FDA,

Proposal to Establish a Monograph for OTC Topical Antimicrobial Products, 39 Fed. Reg. 33103, 33124, 33127 (Sept. 13, 1974) [hereinafter 1974 Proposed Monograph], Ex. 3 to Wang Decl. Noting the increasing prevalence of personal care products containing these chemicals, the agency acknowledged the need for further testing on the safety of repeated and extended use of antimicrobial soaps. *Id.* at 33115. More recently, in a 2009 letter to Representative Edward Markey, the FDA recognized the absence of long-term data "on the effects of dermal application, a known method of triclosan exposure." Letter from Jeanne Ireland, Assistant Comm'r for Legislation, FDA, to Edward J. Markey, Chairman, House Subcomm. on Energy & Env't (Feb. 23, 2010), at 3, *available at* http://markey.house.gov/docs/fdatriclosanresponsereduced.pdf [hereinafter FDA Letter to Markey], Ex. 11 to Wang Decl. The agency also noted the need for more studies on the endocrine disruption potential, as well as the reproductive and developmental toxicity, of triclosan. *See id.*

Many consumers are unaware that triclosan and triclocarban pose serious health risks. Janssen Decl. ¶ 35. In its 1974 report, the FDA noted that "many individuals are involuntarily, unknowing captive consumers of [antimicrobial] soaps." 1974 Proposed Monograph, at 33124. This remains true today. Janssen Decl. ¶ 35.

The Challenged Agency Action

In order to comply with its congressional mandate under the 1962 amendment to the FFDCA, in 1972, the FDA proposed review of all over-the-counter drugs for safety, effectiveness, and labeling accuracy, 37 Fed. Reg. 85, 87 (Jan. 5, 1972), and four months later published final regulations establishing the process for over-the-counter drug review under 21 C.F.R. § 330.10. 37 Fed. Reg. 9464 (May 11, 1972). The FDA appointed a Panel to review data and prepare a report on the safety and effectiveness of over-the-counter drug products containing

antimicrobial ingredients for topical human use. *See* 1974 Proposed Monograph at 33104. The reviewed products included soaps, surgical scrubs, skin washes, skin cleansers, and first-aid preparations. *See id*.

In September 1974, the agency published in the Federal Register the Panel's recommendations and conclusions on antimicrobial ingredients. *Id.* at 33104-40. The FDA also proposed to establish the monograph ("Monograph") specifying what claims manufacturers could make about over-the-counter topical antimicrobial drug products. *See id*. at 33103. The proposed order designated triclosan and triclocarban as Category II ingredients – i.e., not safe and effective, or misbranded – when used in certain health-care personnel products, including patient pre-operative skin preparation and surgical hand scrub. *See id.* at 33115. In addition, it designated as Category III ingredients – i.e., insufficient data for classification – triclosan when used in antimicrobial soap and certain skin antiseptic formulations, and triclocarban when used in bar soap and health-care personnel handwash. *See id.* The FDA proposed to prohibit the continued use of Category II active ingredients six months after publication of the final Monograph, and Category III active ingredients one year after publication. *See id*. at 33103.

Over three years later, in January 1978, the FDA published its first tentative final order for these drug products. FDA, OTC Topical Antimicrobial Products: Tentative Final Order, 43 Fed. Reg. 1210 (Jan. 6, 1978) [hereinafter 1978 Tentative Monograph], Ex. 4 to Wang Decl. The tentative final order identified as Category II and Category III active ingredients the same uses of triclosan and triclocarban as in the agency's 1974 proposal, with a few modifications. *See id.* at 1227 (adding Category II designation for triclocarban in skin wound cleanser formulations other than bar soap); *id.* at 1229-30 (removing Category III classification for triclosan when used in skin wound protectant and adding triclocarban when used in skin wound

cleansers formulated as bar soap). The FDA proposed to eliminate from interstate commerce Category II active ingredients six months after publication of the final Monograph, and Category III active ingredients two years after publication. *See id.* at 1227, 1229.

Even though the 1978 tentative final order categorized both triclosan and triclocarban as Category II and Category III ingredients, *compare* 1974 Proposed Monograph, at 33115, *with* 1978 Tentative Monograph, at 1227, 1229, the agency's failure to issue a final order allowed antimicrobial products containing these chemicals to stay on the market and become increasingly widespread. The agency took no other substantive actions on the Monograph between 1978 and 1994.

In June 1994, approximately sixteen years after issuing its tentative final monograph calling for removal of triclosan products from the market, the FDA published a second tentative final order. 1994 Tentative Monograph at 31402. The new order divided product categories from the 1978 order into two groups: "health-care antiseptics" and "first-aid antiseptics." *Id.* at 31403. The 1994 tentative monograph focused exclusively on "health-care antiseptics," which are products "applied topically to the skin to help prevent infection or to help prevent cross contamination," *id.* at 31437-38. The tentative order designated both triclosan and triclocarban as Category III active ingredients for which there were insufficient data to establish safety and effectiveness. *See id.* at 31436. This designation included antiseptic handwash, which was "used by consumers on a more frequent, even daily, basis and includes products for personal use in the home." *Id.* at 31403. The 1994 order proposed to prohibit the non-monograph (Category II and III) uses from being introduced into interstate commerce one year after publication of the final Monograph. *Id.* at 31403. Therefore, unless sufficient data were introduced to re-classify triclosan and triclocarban as Category I drugs (safe, effective, and not misbranded), over-the-

counter topical antimicrobial drug products containing these chemicals would be prohibited from entering the market one year after finalization of the Monograph.

Between 1994 and 2003, the agency took no further substantive action on the Monograph. In May 2003, the FDA published a notice in the Federal Register reopening the administrative record to accept comments and data concerning over-the-counter healthcare antiseptic drug products. FDA, Health-Care Antiseptic Drug Products: Reopening of the Administrative Record, 68 Fed. Reg. 32003 (May 29, 2003), Ex. 6 to Wang Decl. The comment period closed on August 27, 2003. *Id.* The agency has taken no further action on the Monograph since then.

The FDA has disregarded three requests from plaintiff Natural Resources Defense Council ("NRDC") to provide a concrete schedule for completion of the Monograph. NRDC met with FDA senior staff members in July 2009 and again in September 2009 to ascertain the agency's timeline for finalization. Janssen Decl. ¶ 33. The FDA did not provide a definitive timeframe during these meetings – on the contrary, in the September meeting, the FDA representatives were unaware of the status of the review process or of the persons responsible for the triclosan and triclocarban evaluation. *Id.* Subsequently, NRDC asked the FDA for "a commitment, with timelines, to finalize the draft monograph for topical antimicrobial drug products for over-the-counter human use." Letter from Sarah Janssen, Staff Scientist, NRDC, to Jesse Goodman, Chief Medical Officer, FDA (Sept. 30, 2009), at 2, Ex. 8 to Wang Decl. In its response eight months later, the agency did not commit to a specific deadline for finalizing the Monograph. Letter from Jesse L. Goodman, Chief Scientist, FDA, to Jennifer Sass, Senior Scientist, NRDC (May 28, 2010) [hereinafter FDA Letter to NRDC], at 2, Ex. 9 to Wang Decl.

The FDA has not provided a concrete deadline for finalizing the Monograph even in response to congressional inquiry. In a letter dated January 5, 2010, Representative Markey requested that the FDA provide "a detailed timeline" for its "plan on promulgating finalized rules regarding over the counter topical antimicrobial products." Letter from Edward J. Markey, Chairman, House Subcomm. on Energy & Env't, to Margaret Hamburg, Comm'r, FDA (Jan. 5, 2010), at 3, *available at* http://markey.house.gov/docs/fdatriclo.pdf, Ex. 10 to Wang Decl. The FDA responded that "we cannot give you a detailed timeline for completion of this process" but "are working diligently to publish the proposed rule and will finalize the rule as quickly as possible thereafter." FDA Letter to Markey, at 1. On April 8, 2010, the FDA announced on its website the agency's intention to communicate findings of its review to the public in Spring 2011. FDA Website. However, the agency neither specified what form its findings would take nor provided a deadline for finalization of the Monograph. *See id*.

Sixteen years after publication of the amended tentative final order, thirty-two years after publication of the original tentative final order, and thirty-six years after the initial proposed order, the FDA has yet to finalize the Monograph. Over-the-counter antimicrobial drug products containing triclosan and triclocarban continue to be widely marketed. *See* FDA Letter to Markey, at 6; Janssen Decl. ¶ 12.

SUMMARY OF ARGUMENT

The FDA has a nondiscretionary duty under the FFDCA to review over-the-counter drugs for safety and effectiveness, and the agency must discharge this duty with reasonable dispatch. *See* APA § 706(1). Thirty-six years have elapsed since the FDA first proposed to regulate over-the-counter antimicrobial products containing triclosan and triclocarban. This regulatory delay has permitted a wide array of products containing these drugs to remain on the market, exposing

consumers and the general public to significant health risks including reproductive and developmental harm. A delay of over thirty years in the face of significant threat to human health is unreasonable. Judicial intervention is necessary to compel the FDA to finalize a rulemaking process that was initiated in 1972 and for which the agency issued a proposed order in 1974, a tentative order in 1978, and a second tentative order in 1994. Plaintiff's request for relief is appropriately limited. NRDC does not request that the agency come to a particular decision in the final Monograph, but simply that the agency finalize a rulemaking process that has been pending for over three decades.

ARGUMENT

I. STANDARD OF REVIEW.

Because the FFDCA does not provide a standard for judicial review, the court applies the standards contained in the APA. *See LaFleur v. Whitman*, 300 F.3d 256, 267 (2d Cir. 2002). Under the APA, a court must "compel agency action . . . unreasonably delayed." 5 U.S.C. § 706(1). The Second Circuit takes guidance from D.C. Circuit jurisprudence in adjudicating § 706(1) claims. *See NRDC v. Fox*, 93 F. Supp. 2d 531, 543 (S.D.N.Y. 2000) ("Because [§ 706(1)] is much less frequently invoked than § 706(2)(A), the courts of the Second Circuit . . . have generally looked to D.C. Circuit precedent for guidance."). In evaluating a claim of unreasonable delay, the court examines whether an agency has a duty to act and has delayed unreasonably in discharging that duty. *See In re Bluewater Network*, 234 F.3d 1305, 1315 (D.C. Cir. 2000).

Although an agency "is entitled to considerable deference in establishing a timetable for completing its proceedings," this discretion "is not unbounded, . . . since the consequences of dilatoriness may be great." *Cutler v. Hayes*, 818 F.2d 879, 896 (D.C. Cir. 1987). "[E]xcessive

delay saps the public confidence in an agency's ability to discharge its responsibilities and creates uncertainties for the parties, who must incorporate the potential effect of possible agency decisionmaking into future plans." *Id.* at 896-97. An agency's unreasonable delay "signals the breakdown of regulatory processes," and the court "will interfere with the normal progression of agency proceedings to correct transparent violations of a clear duty to act." *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 418 (D.C. Cir. 2004) (internal citation and quotation marks omitted). In assessing whether such a violation has occurred, the court considers the delay in the context of the relevant statutory scheme and the congressional goals embodied in the statute. *See Hayes*, 818 F.2d at 897-98 & n.156. Evaluation of a claim of unreasonable delay "necessarily turns on the facts of each particular case." *Midwest Gas Users Ass'n v. FERC*, 833 F.2d 341, 359 (D.C. Cir. 1987).

Summary judgment should be granted if "there is no genuine issue as to any material fact" and the moving party "is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 884 (1990); *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 309 (2d Cir. 2008). A "genuine issue" as to material facts exists only "where the evidence, viewed in the light most favorable to the nonmoving party, is such that a reasonable jury could decide in that party's favor." *Guilbert v. Gardner*, 480 F.3d 140, 145 (2d Cir. 2007).

II. THE FDA HAS FAILED TO PERFORM A NON-DISCRETIONARY DUTY TO REGULATE TRICLOSAN AND TRICLOCARBAN.

A. Finalization of Drug Regulation Is a Nondiscretionary Duty.

The FDA's failure to finalize the Monograph is a failure to perform a discrete, nondiscretionary action mandated by 21 U.S.C. § 355. *See Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) ("[A] claim under § 706(1) can proceed only where a plaintiff

asserts that an agency failed to take a *discrete* agency action that it is *required* to take."). The APA provides for judicial review of "unreasonably delayed" agency action. 5 U.S.C. § 706(1); *see also Air Line Pilots Ass'n, Int'l v. Civil Aeronautics Bd.*, 750 F.2d 81, 85 (D.C. Cir. 1984) ("Congress has instructed statutory review courts to compel agency action which has been unreasonably delayed."). "By definition, a claim of unreasonable delay cannot await final agency action before judicial review, since it is the very lack of agency action which gives rise to the complaint." *Id.*

The FFDCA requires the FDA to review over-the-counter drugs for safety and efficacy. *See* 21 U.S.C. § 355(a), (d), (e); *id.* § 393(2)(B); *Hayes*, 818 F.2d at 895 ("[T]he 1962 amendments to the [FFDCA] obligate FDA to review [over-the-counter] drugs for their therapeutic efficacy as well as their safety."). While the FDA has discretion in deciding how to discharge this duty, "the agency lacks authority to simply do nothing to effectuate the purpose of the Act." *Hayes*, 818 F.2d at 895. The drug review program is not voluntary: "Once FDA elected to respond to its legislative directive by establishing the OTC drug review program, the APA imposed an obligation to proceed with reasonable dispatch." *Id.* (citing 5 U.S.C. §§ 555(b), 706(1)).

B. The Agency's Duty Is Not Discharged by Announcements of Plans to Regulate.

The FDA's announcement of plans to communicate "findings" of its review to the public in spring 2011 does not render the agency's delay unreviewable. *See* FDA Website (stating that the agency "will communicate the findings of its review to the public in spring 2011"). Such an "interim date" provides no assurance that the FDA will finalize the Monograph within a reasonable time. *See In re United Mine Workers of Am.*, 190 F.3d 545, 556 (D.C. Cir. 1999) (noting that the agency "provide[d] no end-date at all" and was "unresponsive to [the court's]

order to provide a 'definite schedule'" for issuance of final regulations despite the agency's provision of "interim dates"). Moreover, it is unclear what form the agency's "findings" will take. A mere announcement on the FDA's website or yet another tentative final order, long after two tentative orders have already been issued, constitutes "no end-date at all." *Id.*

Likewise, the FDA's pronouncements that it has been "working diligently," FDA Letter to Markey, at 1, and "as expeditiously as possible," FDA Letter to NRDC, at 2, provide no guarantee that the agency will not continue to delay unreasonably. The FDA's ongoing lack of commitment to a concrete deadline, *see* FDA Letter to Markey, at 1 ("[W]e cannot give you a detailed timeline for completion of this process . . . ."), is emblematic of its failure to regulate and underscores the propriety of this Court's jurisdiction. *See United Mine Workers*, 190 F.3d at 555 ("The problem is that we cannot fairly describe MSHA's schedule as 'reasonably definite.' The agency does not even attempt to characterize the final promulgation date as a reliable estimate. . . . For the foregoing reasons, the court will retain jurisdiction over this case until there is a final agency disposition . . . .").

III. THE FDA'S THIRTY-SIX YEAR DELAY IN FINALIZING THE MONOGRAPH IS UNREASONABLE.

In determining whether an agency's delay is unreasonable, the court must "ascertain the length of time that has elapsed since the agency came under a duty to act." *Hayes*, 818 F.2d at 897. More than three decades have passed since the FDA first proposed to establish the Monograph for triclosan and triclocarban. *See* 1974 Proposed Monograph, at 33103. While there is no per se rule as to what constitutes an unreasonable delay, "a reasonable time for agency action is typically counted in weeks or months, not years." *Am. Rivers*, 372 F.3d at 419 (finding six-year-plus delay "nothing less than egregious" and directing agency to respond to plaintiffs' petition regarding endangered fish listing).

In *Telecommunication Research & Action Center v. FCC* ("*TRAC*"), the D.C. Circuit Court of Appeals provided six criteria by which to assess the reasonableness of agency delay: (1) The time taken to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed, that statutory scheme may supply the content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting action on agency activities of higher or competing priority; (5) the court should evaluate the nature and extent of interests prejudiced by delay; and (6) the court need not find impropriety lurking behind agency lassitude in order to hold that action is unreasonably delayed. 750 F.2d 70, 80 (D.C. Cir. 1984). While these factors are "hardly ironclad," they provide "useful guidance." *Id.*; *accord NRDC v. Fox*, 93 F. Supp. 2d at 543.

Consideration of the *TRAC* factors substantiates the unreasonableness of the FDA's delay in issuing a final regulation for triclosan and triclocarban – unreasonableness that is amplified by the exceptional length of that delay.

A. The FDA's Delay Is Not Governed By a "Rule of Reason."

The "first and most important factor" in assessing reasonableness is whether the time the agency takes to make the decision is "governed by a rule of reason." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008). The FDA's thirty-six year delay since it first proposed to regulate triclosan and triclocarban strains liberal interpretations of reasonableness. *Cf. Pub. Citizen Health Research Group v. Brock*, 823 F.2d 626, 628 (D.C. Cir. 1987) (observing that OSHA plan to finalize ethylene oxide exposure limits after six years "treads at the very lip of the abyss of unreasonable delay").

The length of permissible delay is usually calculated in "weeks or months, not years" – and certainly not decades. *See Am. Rivers*, 372 F.3d at 419. Courts have deemed unreasonable delays of far shorter duration than the delay at issue in this case. *See, e.g.*, *Bluewater Network*, 234 F.3d at 1307 (holding unreasonable Coast Guard's ten-year delay in promulgating compliance standards for tank pressure monitoring devices); *Pub. Citizen Health Research Group v. Auchter*, 702 F.2d 1150, 1157 (D.C. Cir. 1983) ("*Auchter*") (finding that "[t]hree years from announced intent to regulate to final rule is simply too long" in regulating health care industry worker exposure to chemical). In light of its congressional mandate to "keep interstate channels free from deleterious, adulterated and misbranded" drugs, *see United States v. Walsh*, 331 U.S. 432, 434 (1947), the FDA's thirty-six year delay in finalizing the Monograph is not governed by a rule of reason.

B. The FDA's Delay Contravenes the FFDCA Statutory Scheme.

When Congress establishes a timetable or other indication of speed for agency action, the statute helps supply "the rule of reason" governing the pace of agency decisionmaking. *See United Mine Workers*, 190 F.3d at 549; *In re Monroe Commc'ns Corp.*, 840 F.2d 942, 945 (D.C. Cir. 1988) ("Delay is measured by a 'rule of reason,' informed whenever possible by discernible congressional expectations, respecting the pace at which proceedings should advance."). In ascertaining the reasonableness of FDA's delay in finalizing the Monograph, the Court looks to the FFDCA's scheme and goals. *Cf. Auchter*, 702 F.2d at 1158 n.30 ("The reasonableness of the delay must be judged in the context of the statute which authorizes the agency's action." (internal quotation marks omitted)).

The "overriding purpose" of the FFDCA is "to protect the public health . . . and ensure that products marketed "serve the public with efficacy and safety." *Article of Drug*, 394 U.S. at

798; *cf.* Pub. L. No. 87-781, 76 Stat. 780. The public is "not sufficiently protected when violative drugs remain on the market." 37 Fed. Reg. at 86. Congressional desire for timely decisions on drug approval or rejection is discerned in the deadline it set for review of new drug applications – the agency must issue decisions on the safety and efficacy of new drugs within 180 days. 21 U.S.C. § 355(c)(1).

The timelines in the Monograph process reveal a similar desire for the FDA to act with deliberate speed in protecting the public from unsafe or ineffective over-the-counter drugs. Once the agency publishes a proposed order, the public has ninety days to submit comments. 21 C.F.R. § 330.10(a)(6)(iv). Reply comments must be filed thirty days after the initial comment deadline. *Id.* After reviewing the comments, the agency publishes a tentative final monograph, on which the public has ninety days to submit comments. *Id.* § 330.10(a)(7). Within twelve months after publication of the tentative monograph, any interested person can file new data or information with the agency, to which the public has sixty days to respond. *Id.* § 330.10(a)(7)(iii)-(iv). After reviewing these comments and new data, the agency publishes a final monograph. *Id.* § 330.10(a)(9).

The FDA's timetable for submission of comments and orderly progression of proposed, tentative, and final regulation indicates an intent that the over-the-counter drug evaluation process proceeds in an expeditious manner. Once an agency decides to take a particular action, there is a duty to do so within a reasonable time. *Pub. Citizen Health Research Group v. FDA*, 724 F. Supp. 1013, 1020 (D.C. Cir. 1989) (finding seven-year delay in promulgating regulations to be unreasonable after agency had identified health risk). Although the deadlines for comments at each stage of the monograph process are not an express timetable for issuance of a final monograph, the regulations clearly envision that decisionmaking will progress in periods of

months, not decades. *See United Mine Workers*, 190 F.3d at 551; *see also Bluewater Network*, 234 F.3d at 1309 (finding that Coast Guard's episodic promulgation of temporary standards did not satisfy its statutory requirement to adopt final rules governing oil tanker design).

Furthermore, in delaying final action on the Monograph, the agency has permitted the widespread marketing of products containing triclosan and triclocarban despite the products' tentative Category III classification. This effectively nullifies the statutory command that drug products cannot be marketed unless they are safe, effective, and not misbranded – a result that was deemed unlawful by the District Court of the District of Columbia. In *Cutler v. Kennedy*, the court struck down an FDA regulation allowing continued sale of Category III drugs for an indefinite period of time pending new testing. 475 F. Supp. at 855. The district court explained that under the FFDCA, drugs could be marketed only if they are licensed under the new drug process or are generally recognized by experts as safe and effective and therefore not subject to active regulation. *Id.* at 854. The goal of the FFDCA is to "ensure that every marketed drug is safe and effective" and "there are no . . . interim provisions under which safe, but only potentially effective drugs can be marketed." *Id.* FDA's decades-long delay has permitted the indefinite marketing of triclosan and triclocarban products tentatively classified as Category III, exposing the public to potentially unsafe and ineffective drugs. Given the purpose and scheme of the FFDCA, this delay is unreasonable as a matter of law. *See TRAC*, 750 F.2d at 80.

C. The Agency's Delay Should Not be Afforded Deference Because Human Health and Welfare Are at Stake.

The FFDCA was enacted for the protection of the "health of people which, in the circumstances of modern industrialism, are largely beyond self-protection." *United States v. Dotterweich*, 320 U.S. 277, 280 (1943). Courts have consistently recognized that regulatory "delays that might be reasonable in the sphere of economic regulation are less tolerable when

human health and welfare are at stake." *Core Commc'ns*, 531 F.3d at 855. Judicial intervention in an agency's pace of rulemaking is necessary when the "very purpose of the governing Act is to protect . . . lives." *Auchter*, 702 F.2d at 1157-58; *see also Hayes*, 818 F.2d at 898 ("The deference traditionally accorded an agency to develop its own schedule is sharply reduced when injury likely will result from avoidable delay.").

In *Auchter*, the court credited the plaintiffs' claims that the exposure of workers to ethylene oxide posed a "serious risk of causing chromosomal abnormalities and cancer" and concluded that a three-year delay between the petition and the projected final regulation was "not tolerable." 702 F.2d at 1153-54. In another case involving harm to human health, the court found a seven-year delay in FDA regulation to be "wholly unreasonable and unacceptable" because it exposed women to the risk of Toxic Shock Syndrome, a potentially fatal disease caused by a bacterium linked to tampon usage. *Pub. Citizen Health Research Group v. FDA*, 724 F. Supp. at 1021.

In this case, the FDA has acknowledged both that the threats to human health exist and that a high number of consumers are exposed to these risks, yet it continues to postpone issuance of a final regulation. In its 1974 tentative monograph, the FDA expressed concern about increased human blood levels of triclosan resulting from "widespread use of antimicrobials in soaps" and about "the possible future proliferation of [triclocarban] use in various OTC products, thereby increasing the possible total body burden." 1974 Proposed Monograph, at 33107, 33124. The agency's 1978 tentative final order noted that health-care personnel may use triclosan handwashes "as often as 50 to 100 times daily." 1978 Tentative Monograph, at 1214. In its letter to Representative Edward Markey earlier this year, the FDA stated its belief that "the majority of consumer antibacterial soaps contain triclosan or triclocarban as active ingredients"

and that "existing data raise valid concerns about the effects of repetitive daily human exposure to these antiseptic ingredients [i.e., triclosan and triclocarban]." FDA Letter to Markey, at 2.

At each stage of the proposed and tentative rulemaking process, the FDA has acknowledged that based on available scientific evidence, triclosan and triclocarban are not safe and effective (Category II designations), or there are insufficient data to evaluate safety and effectiveness (Category III). *See* 1974 Proposed Monograph, at 33115; 1978 Tentative Monograph, at 1227, 1229; 1994 Tentative Monograph, at 31436. In 1974, the agency acknowledged a study linking triclocarban with brain and spleen changes and stated that this potential health effect "is of such importance that it cannot be ignored." 1974 Proposed Monograph, at 33124. The same report also identified potential testicular and liver damage resulting from triclosan and triclocarban exposure. *Id.* at 33124, 33127. In the tentative monograph issued in 1978, the agency acknowledged that triclosan and triclocarban have a more severe effect on infants because their bodies lack detoxification mechanisms present in adults. The scientific Panel reviewing the drugs recommended the use of a product warning label: "Not to be used on infants under 6 months of age." 1978 Tentative Monograph, at 1233-34. These labels are not currently in use. Janssen Decl. ¶ 20.

The FDA also recognized that, in addition to potential damage to organs, triclocarban is linked to methemoglobinemia, a blood disorder that interferes with oxygen delivery. Because high temperature decomposition of triclocarban produces a chemical that can induce this blood disorder, the scientific Panel cautioned that soap or soap products containing triclocarban should not be heated and subsequently used on the human body. 1974 Proposed Monograph, at 33125. In the absence of final regulation, these products do not currently carry warning labels against being heated before use. *See* Janssen Decl. ¶ 24.

Substantial evidence indicates that triclosan and triclocarban may have endocrine-disrupting properties that affect reproduction and development. *See* Janssen Decl. ¶¶ 16-31; FDA Letter to Markey, at 2 ("FDA shares your concern over the potential effects of triclosan and triclocarban as endocrine disruptors . . . for example, [the chemicals] decrease[] thyroxine levels . . . the levels of androgens . . . [and] sperm production."). The agency is also aware of the potential role played by these drugs in the development of antibiotic-resistant bacteria. *See, e.g.*, 1974 Proposed Monograph, at 33128; FDA Letter to Markey, at 6-7. The widespread use of products containing triclosan and triclocarban may exert selective evolutionary pressure favoring bacterial strains that are impervious to these chemicals, and bacteria that develop resistance to these chemicals may also form "cross-resistance" to antibiotics used to treat infections. Janssen Decl. ¶ 25.

Antimicrobial products containing triclosan and triclocarban are unsafe and ineffective or, at best, there are insufficient data to determine their safety and effectiveness. *See* 1994 Tentative Monograph; c*f. NRDC v. Am. Petroleum Inst.*, 595 F. Supp. 1255, 1269 (S.D.N.Y. 1984) (noting that EPA's publication of proposed test rules indicated belief that chemicals covered by proposed rules presented unreasonable human health risks). Unlike a situation where judicial interference merely reshuffles agency priorities for the economic benefit of a pharmaceutical company, *see In re Barr Laboratories*, 930 F.2d 72, 75 (D.C. Cir. 1991), in this case the FDA's delay exposes "a significant portion of the U.S. population, both children and adults," to chemicals linked to developmental and reproductive disorders. *See* FDA Letter to Markey, at 3; Janssen Decl. ¶¶ 16-30. The agency's failure to finalize the Monograph jeopardizes "human health and welfare" and is therefore unreasonable. *See TRAC*, 750 F.2d at 80.

D. Justifications of Regulatory Complexity Are Unpersuasive in Light of the Thirty-Six Year Delay.

Agency justifications for delay based on the "difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources . . . become less persuasive as delay progresses, and must always be balanced against the potential for harm." *Hayes*, 818 F.2d at 898. When the consequences of agency delay include significant threat to human health, the "complexity of the task confronting the agency . . . is not always sufficient to justify lengthy delays." *Id.* In *United Mine Workers*, the court found that the agency unreasonably delayed issuance of final regulations governing coal miner exposure to diesel engine emissions. 190 F.3d at 554. The D.C. Circuit Court of Appeals acknowledged the agency's claim of competing regulatory needs but stated that "however many priorities the agency may have, and however modest its personnel and budgetary resources may be, there is a limit to how long it may use these justifications to excuse inaction in the face of the congressional command to act." *Id.*

The FDA's tentative regulations and its correspondence with Congressman Markey suggest that the agency is aware of the pressing health concerns posed by the proliferation of antibacterial products on the market. *See supra* section III.C. The agency's other duties do not excuse its decades-long delay, particularly in light of the agency's own acknowledgment of the widespread exposure and significant risks to public health posed by triclosan and triclocarban. *Cf. In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992) ("We are not unmindful of OSHA's need to juggle competing rulemaking demands on its limited scientific and legal staff, but we think the delay in promulgating a final rule that OSHA believes is necessary to workers' well-being has been too lengthy for us to temporize any longer."); *Farmworker Justice Fund, Inc. v. Brock*, 811 F.2d 613, 632-33 (D.C. Cir. 1987) (recognizing

agency's limited resources and competing priorities but finding fourteen-year delay in setting fieldworker sanitation standards to be unreasonable).

E. NRDC is Prejudiced by the Delay.

The "nature and extent of the interests prejudiced by delay" further supports a finding of unreasonable agency delay. *Core Commc'ns*, 531 F.3d at 855 (citing *United Mine Workers*, 190 F.3d at 549). Until FDA finalizes its Monograph, NRDC's members continue to be exposed to triclosan and triclocarban in their homes and workplaces. *See* Declaration of Diana Owens ("Owens Decl.") ¶¶ 9-17 (veterinary technician member describing inability to limit her exposure to triclosan hand and dish soaps at her workplace); Declaration of Megan Schwarzman ("Schwarzman Decl.") ¶¶ 8-9 (physician discussing prevalence of triclosan hand soap at hospital where she works). Each increment of exposure to triclosan and triclocarban increases the total body burden and risk to human health. *See* Janssen Decl. ¶¶ 30-32. The agency's failure to finalize the Monograph prolongs exposure to sources of triclosan and triclocarban that are identifiable and for which substitute products are available. *Id.* ¶ 32; Schwarzman Decl. ¶¶ 14-16.

The prevalence of triclosan and triclocarban in personal care and home goods products makes it difficult for consumers to avoid exposure to these chemicals. According to a physician-performed survey cited by the FDA, of "national brand soaps (plain and antibacterial) available at national chains, regional grocery and Internet stores, triclosan or triclocarban was found in 76 percent of 395 liquid and 29 percent of 733 bar soaps." FDA Letter to Markey, at 6. Plaintiff's interests are further prejudiced because it cannot challenge, on the basis of an administrative record, the continued marketing of unsafe products. The result of the FDA's inaction is the widespread marketing and use of products containing triclosan and triclocarban – a de facto

classification of the products as Category I drugs that are safe, effective, and not misbranded. Yet the absence of a final Monograph prevents plaintiff and other interested parties from challenging the merits of the determination that these products should be permitted on the market. *Cf. Am. Broadcasting Co. v. FCC*, 191 F.2d 492, 501 (D.C. Cir. 1951) ("Agency inaction can be as harmful as wrong action. The [FCC] cannot, by its delay, substantially nullify rights which the [statute] confers, though it preserves them in form.").

F. NRDC Need Not Show Agency Impropriety.

The Court "need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed." *Core Commc'ns*, 531 F.3d at 855 (internal quotation marks omitted). Since 1974, the FDA has acknowledged and credited scientific studies demonstrating significant health harms of triclosan and triclocarban, including infertility, thyroid hormone disruption, and the development of antibiotic-resistant bacteria. *See supra* section III.C; Janssen Decl. ¶¶ 16-26. FDA's inaction permits these products to be marketed widely despite their tentative monograph status as Category II and III ingredients – unsafe and ineffective. An agency's discretion is not unbounded, *Pub. Citizen Health Research Group v. FDA*, 724 F. Supp. at 1020, and the thirty-six year delay since the FDA's initial proposed regulation is unreasonable.

IV. NRDC'S CLAIMS ARE PROPERLY BEFORE THE COURT.

A. NRDC Has Standing to Challenge the FDA's Delay.

To establish Article III standing, an associational plaintiff must show that (1) its members would have standing to sue in their own right; (2) the interests it seeks to protect are germane to its organizational purposes; and (3) the litigation will not require its members' individual participation. *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977); *Bldg. &*

Constr. Trades Council v. Downtown Dev., Inc., 448 F.3d 138, 144 (2d Cir. 2006). NRDC satisfies this three-part test.

NRDC's members would have standing on their own because they suffer concrete, particularized, and imminent "injury in fact" that is fairly traceable to the FDA's delay and likely to be redressed by a favorable judicial decision. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc. (TOC)*, 528 U.S. 167, 180-81 (2000).

NRDC's members include consumers and healthcare professionals who are worried about their exposure to over-the-counter topical antimicrobial products containing triclosan or triclocarban. Their injury is both cognizable and clear. Numerous studies have suggested that these chemicals pose significant health risks. Janssen Decl. ¶¶ 16-26. NRDC's members have reasonable concern and anxiety about potential harm to themselves and their families from exposure to triclosan and triclocarban in drug products covered by the Monograph. Owens Decl. ¶¶ 4-5, 15-16, 19, 21; Schwarzman Decl. ¶¶ 6-7, 10-12. Continued exposure to these chemicals and uncertainty about that exposure are sufficient injuries for standing purposes. *See, e.g.*, *Laidlaw*, 528 U.S. at 184-85 (finding injury where citizens' fear over contamination of river caused them to curtail recreational activities); *N.Y. Pub. Interest Research Group v. Whitman*, 321 F.3d 316, 325 (2d Cir. 2003) (holding that plaintiffs had a cognizable injury despite uncertainty over extent of their exposure to air pollutants); *Baur v. Veneman*, 352 F.3d 625, 628, 633-34 (2d Cir. 2003) (noting that increased risk of disease from potentially contaminated beef formed a cognizable injury); *LaFleur*, 300 F.3d at 270-71 (finding plaintiff alleged sufficient injury from exposure to sulfur dioxide emissions, even if those emissions are below federal limits).

The injuries of NRDC's members are directly traceable to the FDA's delay. But for that

delay, individuals would either be spared prolonged, potentially dangerous exposures to triclosan and triclocarban in over-the-counter antimicrobial drug products or have the FDA's reassurance that these products are generally recognized to be safe, effective, and accurately labeled. A ruling in NRDC's favor will redress the injuries to its members by creating a concrete deadline for achievement of one of these outcomes.

The suit is germane to NRDC's institutional mission. *See* Declaration of Linda Lopez ¶ 6 (stating that NRDC's mission includes the "prevention and mitigation of . . . health threats posed by toxic chemicals in order to protect and maintain NRDC members' health"). Finally, because NRDC seeks only declaratory relief and the imposition of a regulatory deadline, participation of individual members is not required. *Bldg. & Constr. Trades Council*, 448 F.3d at 150 (finding third prong of associational standing test satisfied where organization "seeks a purely legal ruling without requesting . . . individualized relief" for its members).

B. NRDC Need Not Exhaust Administrative Remedies.

There is no jurisdictional requirement that parties exhaust administrative remedies before seeking judicial review. *Hayes*, 818 F.2d at 890 ("[T]he doctrine is not linked to the power of the court to entertain actions, but instead implicates prudential considerations . . . ."). Rather, exhaustion doctrine "should be applied "flexibly, with an eye toward its underlying purposes." *Id.* These purposes include:

> (1) discouraging the "frequent and deliberate flouting of administrative processes;" (2) protecting agency autonomy by allowing an agency the first opportunity to apply its expertise, exercise its discretion, and correct its errors; (3) aiding judicial review by promoting the development of facts during the administrative proceeding; and (4) promoting judicial economy by reducing duplication, and perhaps even obviating judicial involvement.

Id. at 890-91.

Judicial review of the FDA's unreasonable delay does not frustrate the purposes of exhaustion doctrine. First, NRDC does not seek to circumvent the FDA's "administrative processes," *id.* at 890; it merely seeks to expedite them. Second, intervention by courts causes minimal interference with administrative autonomy in § 706(1) cases. *See id.* ("[J]udicial review of claims of unreasonable delay [does] not prematurely inject the courts into the agency's consideration of the merits of the issue before it."); *accord Coit Indep. Joint Venture v. Fed. Sav. & Loan Ins. Corp.*, 489 U.S. 561, 587 (1989) (refusing to require exhaustion of administrative remedies where administrative process subjects plaintiffs to unreasonable delay or to an indefinite timeframe for decision). By imposing a date certain by which the FDA must finalize its regulation, the Court neither dictates the substance of the final Monograph nor interferes with the agency's scientific and technical expertise; the FDA retains complete discretion over the determination of whether products containing triclosan and triclocarban are safe, effective, and accurately labeled. *Cf. Am. Rivers*, 372 F.3d at 419 ("We are not concerned here with what answer FERC might ultimately give the petitioners; rather we are reviewing its failure to give them *any* answer for more than six years.").

Finalization of the Monograph will only aid judicial review of any subsequent challenges to the substance of the regulation, since the "benefits of agency expertise and creation of a record will not be realized if the agency never takes action." *TRAC*, 750 F.2d at 79. NRDC merely asks that the Court compel the FDA to apply its expertise and complete its administrative record – as delineated by the agency's own regulations – in a timely manner. Moreover, judicial intervention is the only means through which NRDC can ensure that, after a delay of more than thirty years, the FDA will fulfill its statutory obligation to regulate over-the-counter microbial products for safety, effectiveness, and accuracy of labeling.

V. NRDC REQUIRES PROMPT RESOLUTION OF ITS CLAIM FOR RELIEF.

This Court's timely intervention is required to effectuate the unequivocal will of Congress to protect public health. The FDA's thirty-six year delay in finalizing the Monograph exceeds even the most generous interpretations of reasonableness. The agency's continued delay defies the joint mandate of the FFDCA and APA and endangers the consumers Congress directed the agency to protect.

Prompt resolution is essential to prevent further harm to NRDC's members and the broader public. This harm is already ongoing. The longer the FDA delays in finalizing the Monograph, the longer consumers will be exposed to triclosan- and triclocarban-containing products whose safety and effectiveness remain unproven. *See* Janssen Decl. ¶¶ 30-32, 34-35. The aggregate exposure from these endocrine-disrupting chemicals increases the risk of serious health effects. *Id.* ¶ 30.

NRDC has raised a purely legal question capable of prompt, definitive resolution. The issue before the Court is whether the FDA's failure to finalize the Monograph after thirty-six years constitutes an unreasonable delay, despite limited agency resources and in light of significant potential risks to human health. There is no material fact in issue; the parties have competing views of the law. Once briefing is complete, the case will be ripe for resolution.

There is a statutory as well as a logical reason to expedite a decision on NRDC's claim for relief. Under 28 U.S.C. § 1657(a), "the court shall expedite the consideration of any action" on a showing of "good cause." Good cause includes a strong public interest in enforcement of a statute. *See* H. Rep. No. 98-985, at 6 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 5779, 5784. Enforcement of the FFDCA will vindicate the compelling public interest in ascertaining that consumer products are safe, effective, and accurately labeled.

Each incremental reduction in avoidable exposure to triclosan and triclocarban reduces the risk of harm to human health, underscoring the urgency of the need for agency regulation. *See* Janssen Decl. ¶ 32. The Court must "set a clear end point to the regulatory snarl" that has delayed the finalization of the Monograph, *Brock*, 823 F.2d at 629, and expedite review and rule on this motion for summary judgment as soon as possible after briefing is complete.

CONCLUSION

For the reasons set forth above, NRDC urges the Court to find that the FDA has unreasonably delayed its promulgation of the Monograph, and to compel the agency to finalize the Monograph within 90 days of the Court's grant of relief.

Respectfully submitted,

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